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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,711	03/19/2004	John S. Fisher	1139.20.DIV2	2710
21901	7590	11/18/2004	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/708,711		FISHER, JOHN S.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Charles A. Marmor, II		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 9 is/are rejected.
- 7) ☒ Claim(s) 3-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Priority*

1. Applicant's claim for the benefit of an earlier filing date under 35 U.S.C. 120 appears to erroneously cite the wrong patent number for a parent application of the instant application. Specifically, Applicant states that the present application is a divisional application of U.S. Serial No. 10/065,155 *which is a continuation-in-part of U.S. Patent No. 6,592,608 that issued on July 15, 2003*. However, U.S. Serial No. 10/065,155 recites that application is a continuation-in-part of U.S. Serial No. 09/682,252, filed on August 9, 2001, which is now abandoned. U.S. Serial No. 09/683,282, which matured into U.S. Patent No. 6,592,608, is drawn to a bioabsorbable sealant that appears unrelated to the instant invention.

In view of the foregoing, Paragraph [0002] of the specification of the present application should be amended to reflect the appropriate parent application number for which the benefit of an earlier filing date under 35 U.S.C. 120 is claimed. Furthermore, said paragraph should be updated to include the current status of all the parent application cited therein.

The Application Data Sheet filed March 19, 2004 also cites the wrong application serial number and patent number under the Continuing Data section. An application data sheet identifying this application by application number and filing date, and correcting the erroneous continuity data citation is required.

***Specification***

2. The disclosure is objected to because of the following informalities:
  - a. In paragraph [0008], line 17, --slides-- apparently should be inserted following “on”.
  - b. In paragraph [0028], line 5, “if” apparently should read --of--.Appropriate correction is required.
3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

4. Claim 1 is objected to because of the following informalities:
  - a. In line 4, “its extent” apparently should read --an extent thereof--.
  - b. In lines 5-6, “that scrapes” apparently should read --adapted to scrape--.
  - c. In line 14, --first-- apparently should be inserted before “slot”.
  - d. In line 15, --first-- apparently should be inserted before “slot”.
  - e. In line 18, “that scrapes” apparently should read --adapted to scrape--.
  - f. In lines 32-33, “that scrapes” apparently should read --adapted to scrape--.Appropriate correction is required.

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5. Claim 3 is objected to because of the following informalities: in line 2, “an exterior” apparently should read --said exterior--. Appropriate correction is required.
6. Claim 5 is objected to because of the following informalities: in line 2, “an exterior” apparently should read --said exterior--. Appropriate correction is required.
7. Claim 7 is objected to because of the following informalities: in line 1, “means” apparently should be deleted. Appropriate correction is required.
8. Claim 8 is objected to because of the following informalities: in line 1, “means” apparently should be deleted. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
10. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim language renders the claim indefinite. It is unclear whether the limitation “said slot” recited in line 1 is intended to refer to the first slot or the second slot.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. ('543). Anderson teaches a needle for fine needle aspiration and core biopsy devices. The needle **400** is of elongate, hollow construction and has a proximal end and a beveled distal end **407**. The wall **405** of needle has a uniform diameter along its extent. The beveled distal end **407** forms a first sharp edge that is capable of scraping or cutting tissue when the needle is displaced from a proximal position to a distal position. A plurality of slots are formed in the wall of the needle. A first slot (the distalmost slot **402** on the upper side of the longitudinal axis as viewed in the cross-section of Fig. 4A) is formed in the needle near the beveled distal end. The first slot is transversely disposed relative to a longitudinal axis of the needle and, when viewed according to the cross sectional view of Fig. 4A, is angled relative to a transverse axis of the needle such that a bottom of the first slot is positioned distal to an opening of the first slot. The opening of the first slot is in open communication with an exterior surface of the needle. The first slot forms a second edge on the needle wall (Fig. 4A) that appears to be sufficiently sharp to be capable of scraping or cutting tissue when the needle is displaced from a distal position to a proximal position. A second slot (the distalmost slot **402** on the lower side of the longitudinal axis as viewed in the cross-section of Fig. 4A) is formed in the needle in longitudinally spaced relation to the first slot. The second slot is transversely disposed

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relative to a longitudinal axis of the needle and, when viewed according to the cross sectional view of Fig. 4A, is angled relative to a transverse axis of the needle such that a bottom of the second slot is positioned proximal to an opening of the second slot. The opening of the second slot is in open communication with an exterior surface of the needle. The second slot forms a third edge on the needle wall (Fig. 4A) that appears to be sufficiently sharp to be capable of scraping or cutting tissue when the needle is displaced from a proximal position to a distal position. Means for communicating a vacuum to a proximal end of the needle 770 are provided so that tissue scraped by the first and third sharp edges during proximal-to-distal travel of the needle is pulled into a lumen of the needle and so that tissue scraped by the second sharp edge during the distal-to-proximal travel of the needle is also pulled into the lumen. The slots have a circumferential extent of about one half the circumference of the needle. A material to which tissue clings may be applied to the first, second and third sharp edges.

*Allowable Subject Matter*

13. Claims 3-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or fairly suggest an aspiration biopsy needle, as



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claimed by Applicant, with a first slot transversely disposed relative to the longitudinal axis of the needle and angled relative to a transverse axis of the needle, such that a bottom of the first slot is positioned distal to an opening of the first slot so a second sharp edge is formed for scraping tissue upon distal-to-proximal displacement of the needle and with a second slot transversely disposed relative to the longitudinal axis of the needle, longitudinally spaced from the first slot, and angled relative to a transverse axis of the needle, such that a bottom of the second slot is positioned proximal to an opening of the second slot so a third sharp edge is formed for scraping tissue upon proximal-to-distal displacement of the needle, and where at least one of the following structural conditions are present: the second sharp edge is elevated with respect to an exterior surface of the needle; the third sharp edge is elevated with respect to an exterior surface of the needle; the second sharp edge is recessed with respect to an exterior surface of the needle; the third sharp edge is recessed with respect to an exterior surface of the needle; the second sharp edge is mounted to a hinge that enables pivotal movement of the second sharp edge; and the third sharp edge is mounted to a hinge that enables pivotal movement of the third sharp edge.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vijfvinkel ('111) teach a vitreous removing apparatus having transverse slots. Weaver ('112) teaches a biliary biopsy needle having transverse slots. Goldsmith ('867) teaches an aspiration biopsy instrument. Lovato et al. ('751) teach an apparatus for transurethral resection including a cannula having a plurality of transverse



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slots. Fisher ('408) teaches a dual action aspiration biopsy needle having a single transverse slot.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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November 15, 2004